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MAR 8 2002

510 (k) SUMMARY

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**1.0 APPLICANT:**

Dr. POONSUK CHERDKIATGUMCHAI  
SIAM SEMPERMED CORPORATION., Ltd.  
110 MOO 8 KANJANAVANIT ROAD  
PATHONG HATYAI SONGKHLA  
THAILAND 90230  
TEL: 66 074 291 648 OR 291 649  
FAX: 66 074 291 650

**2.0 CONTACT PERSON**

Dr. POONSUK CHERDKIATGUMCHAI  
SIAM SEMPERMED CORPORATION., Ltd.  
110 MOO 8 KANJANAVANIT ROAD  
PATHONG HATYAI SONGKHLA  
THAILAND 90230  
TEL: 66 074 291 648 OR 291 649  
FAX: 66 074 291 650

Mrs. KATIE LEVINSON  
SEMPERMED USA Inc.  
30798 US Hwy. 19 N  
Palm Harbor,  
USA FL 34684  
TEL: 727 787 7250  
FAX: 727 787 7558

**3.0 Device Class: I****Product code: 80LYY**

**4.0 Specification:** Latex patient examination glove , Powder free coated , Non chlorinated -Class I 80LYY  
meets all of the requirements of ASTM standard D3578-00

**5.0 Device Description:** Latex Patient Examination glove , Powder free coated , Non chlorinated , non sterile  
(White)

50 micrograms or less of total water extractable protein per gram

**6.0 Intended use:** A patient examination glove is a disposable device intended for medical purposes that is worn  
on the examiners hand or finger to prevent contamination between patient and examiner.

**7.0 Surface treatment:** polymer coated

**8.0 Primary Dermal Irritation in Rabbits Guinea Pig Sensitization (Buehler) : Consumer Product Testing Co.**  
**Experiment reference number : T00-0175 , T01-0112**

**Conclusion :** According to Federal Hazardous Substances Act Regulation , (16 CFR 1500.41), and under the  
conditions of this test , This test article is not a primary dermal irritant  
: This test article is not a sensitizer in guinea pigs, under condition of this test.

KO13261

Siam Sempermed  
Corp., Ltd.

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**510 (k) SUMMARY**

*CONFIDENTIAL*

**9.0 QUALITY CHARACTERISTICS**

|                       |   |
|-----------------------|---|
| Dimensions            | Meet ASTM D 3578-00                     |
| Physical Properties   | Meet ASTM D 3578-00                     |
| Protein content       | 50 ug/g or less                         |
| Residue Powder        | Meet ASTM D 3578-00                     |
| Freedom from pinholes | Meet ASTM D 3578-00<br>Meet ASTM D 5151 |

**10. Conclusion:** Siam Sempermed Latex Patient Examination Glove ,Powder free coated Glove , Non chlorinated (White)

meet the ASTM standard or equivalent standard

meet pinhole FDA requirements

meet labeling claims (see 5.0 and 6.0 above)

*P. Cherdkiatgumchai*

Dr. POONSUK CHERDKIATGUMCHAI  
Chief Quality Officer  
August 22 ,2001



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 8 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Siam Sempermed Corporation, Limited  
C/O Ms. Katie Levinson  
Sempermed USA, Incorporated  
30798 US Highway 19 North  
Palm Harbor, Florida 34684

Re: K013267

Trade/Device Name: Powder Free (polymer Coated) Non-Chlorinated White Latex  
Examination Gloves with Protein Content Labeling Claim ( 50 Micrograms or Less)  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LYY  
Dated: February 14, 2002  
Received: February 25, 2002

Dear Ms. Levinson :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

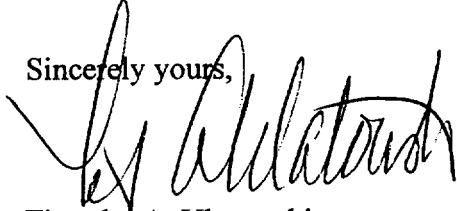
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski

Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## **INDICATION FOR USE**

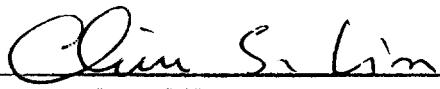
Applicant: Siam Sempermed Corp., Ltd.

510(k) Number: 013267

Device Name: Latex Examination Glove, Powder-Free, Coated, Non-Chlorinated, White with a Protein Content of 50 Micrograms or Less of Total Water Extractable Protein per Gram

### Indications For Use:

A Patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. (21CFR 880.6250)

  
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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number 013267

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)